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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/595,619	05/01/2006	Heinz Von Der Kammer	2335.0160000/SRL/KPQ	3638
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VENABLE LLP P.O. BOX 34385 WASHINGTON, DC 20043-9998				
EXAMINER				
MARVICH, MARIA				
ART UNIT		PAPER NUMBER		
1633				
MAIL DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/595,619

Applicant(s)

VON DER KAMMER ET AL.

Examiner

MARIA B. MARVICH

Art Unit

1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF 298)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Claims 1-28 are pending in this application and subject to the following restriction.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, Claims 1-3, 17 and 25, drawn to a method and kits for detecting DAX-1 transcripts.

Group II, Claims 1-3, 14, 17, 18 and 25, drawn to methods and kits for detecting DAX-1 protein.

Group III, Claims 4-8, 11, 12, 19-23 and 26, drawn to transgenic animals comprising DAX-1 and methods of using.

Group IV, Claim 9, drawn to modulators of DAX-1 RNA or proteins.

Group V, Claims 10 and 24, drawn to methods of screening for modulators of DAX-1 genes.

Group VI, Claims 10 and 24, drawn to methods of screening for modulators of DAX-1 RNA.

Group VII, Claims 10, 15 and 24, drawn to methods of screening for modulators of DAX1- protein.

Group VIII, Claims 13 and 27, drawn to assays for binding to DAX-1.

Group IX, Claims 16 and 28 drawn to immunochemical analysis of DAX-1.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the “special technical feature” of Group I determining DAX-1 RNA levels which does not share a technical feature with Group II which is drawn to methods and kits for detecting DAX-1 protein. While both methods are related by being directed to DAX-1, neither uses any of the same components or steps to detect RNA or protein. Furthermore, McCabe et al (US 6,465,627; see figure 12) teach that DAX-1 RNA and protein sequences are known and hence the technical feature of Groups I and II, DAX-1 lacks novelty of inventive step and does not make a contribution over the prior art. Hence these Groups lack unity of invention.

Groups I, II and IV-IX lack unity with Group III as unity exists if there is evidence which would lead one to conclude that the characteristic of the final product (the transgenic animal) which is the inventive feature in the case is due to the intermediate (the DNA sequence). As no such evidence exists then there is no unity on the basis of an intermediate-final product relationship.

The modulators of DAX-1 (Group IV) are compounds and molecules that are structurally and functionally distinct from Groups I-III and furthermore do not share a technical feature with any of the other Groups.

The methods of Groups V-VII are drawn to respectively, methods of screening for modulators of DAX-1 gene, RNA and protein. The methods are unrelated to those of Groups I and II as the steps aside from use of DAX-1 RNA or protein, which was shown to lack novelty over McCabe et al, are unrelated to those of Groups I and II. As well, the methods of Groups V-VII are distinct as from one another and do not share a technical feature as the methods of screening for modulators of DAX-1 gene use distinct compounds as well as steps to identify the gene as well as distinct reagents from methods of screening modulators of DAX-1 RNA or protein.

The binding assays of Group VIII are related to Groups II and VII by virtue of relationship to DAX-1 protein. However, as McCabe teaches this feature lacks novelty of inventive step and does not make a contribution over the prior art. Hence these Groups lack unity of invention. The binding assays of Group VIII are unrelated to any of Groups I, III-VI and IX as these groups do not share a technical feature.

Finally, group IX, which is drawn to immunocytochemical staining of cells for DAX-1 does not share a special technical feature as antibodies are structurally and functionally distinct from DAX-1 RNA, protein or genes. While the inventions of Groups II, VII and VIII are DAX-1 polypeptides, the DAX-1 polypeptide of Group IX encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of Groups II, VII and VIII and the antibody of Group IX are structurally distinct molecules. Hence, the Groups do not share a technical feature.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD
Examiner
Art Unit 1633

/Maria B Marvich, PhD/
Primary Examiner, Art Unit 1633